DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group IV (claims 51-61) in the reply filed on 11 February 2008 is acknowledged. The traversal is on the ground(s) that examination of all inventive groups presented in the current application would not place a serious burden on the examiner, and thus the restriction was improper, relying on M.P.E.P. §803.

This is not found persuasive because the instant application was filed under the provisions of 35 U.S.C. §371, and the restriction requirement was based on a finding of lack of unity between the disclosed inventions. The discussion of unity of invention under the Patent Cooperation Treaty Articles and Rules as it is applied as an International Searching Authority, International Preliminary Examining Authority, and in applications entering the National Stage under 35 U.S.C. 371 as a Designated or Elected Office in the U.S. Patent and Trademark Office is covered in M.P.E.P. §1850 and is dictated by PCT Rules 13.1 and 13.2. See M.P.E.P. §801. Burden is not a consideration in a finding of lack of inventive unity; rather, according to M.P.E.P. §1850, the only consideration is whether the inventions share a special technical feature. Applicants have not set forth any evidence or reasoning to show that the claimed inventions did share a special technical feature which provided a contribution over the art, and thus the lack of unity holding is maintained. The requirement is still deemed proper and is therefore made FINAL.

With regards to the election of species requirements (set forth on Page 4 of the Restriction Requirement), the Response of 11 February 2008 failed to elect species from each group for examination. A telephone call was made to George Chaclas on 8 May 2008, inviting Applicants to make the required elections telephonically, Mr. Chaclas made a provisional election of endothelial cells as the species of

cells, fibrin as the species of matrix materials, and growth factors as the additional component to be included as the 'second component'. Affirmation of this election must be made by applicant in replying to this Office action.

Claims 1-50 and 62 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions. Claims 1-62 remain pending, of which claims 51-61 have been considered on the merits.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 371, which papers have been placed of record in the file, the instant application is a national stage entry of PCT/US03/352593, filed on 10/16/2003. Additionally, acknowledgment is made of applicant's claim for priority under 35 USC 119(e) to provisional application 60/419,052, filed 10/16/2002.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 4/15/2005 has been received and the references listed thereon have been considered by the examiner. However, the listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892 or provided on the IDS submitted 4/15/2005, they have not been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 51-61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants' claim 51 is directed to a method of increasing endothelialization across an aneurysm ostium, comprising: identifying an aneurysm, endovascularly administering to the aneurysm an aneurysm maintenance device, wherein the device is coated with a biocompatible material comprising cells, and forming a polymer scaffold comprising said cells.

Claim 51 is found indefinite because it is unclear how and/or where the polymer scaffold is formed. It is unclear if the polymer scaffold is part of the aneurysm maintenance device (*i.e.* the polymer scaffold is formed from the biocompatible material comprising the cells) or if it is separate from the aneurysm maintenance device, if it is separate, it is not clear what it is made of or where it is relative to the aneurysm site.

Furthermore, in claim 51 it is unclear how the steps of the method increase endothelialization across the aneurysm ostium (as recited in the preamble). There is no clear correlation between any of the steps and an increase in endothelialization.

Claim 57 is found indefinite, as it recites "wherein the cells form a confluent layer", but fails to disclose *where* the confluent layer of cells is formed (*i.e.* on the aneurysm maintenance device, in/on the polymer scaffold, the surrounding tissue, etc).

Furthermore, in claim 58, the limitation "the existing cell wall" lacks antecedent basis. It is not clear if the existing cell wall refers to the cell wall of the blood vessel, or if reference is being made to a different cell wall.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 51-61 are rejected under 35 U.S.C. 102(b) as being anticipated by Helm et al (US Patent 6,096,021).

Helm et al disclose a double balloon technique for occluding aneurysms, the method comprises introducing a first balloon into a cavity of an aneurysm (in a blood vessel); filling the first balloon with an occluding agent; introducing a second balloon into the blood vessel; inflating the second balloon such that it substantially seals the ostium (neck) of the aneurysm; then rupturing the first balloon to release the occluding agent into the aneurysm cavity; once the occluding agent is stabilized in the aneurysm cavity, deflating and removing the second balloon; finally, optionally removing the first balloon (See Helm et al, col. 4, ln 30-col. 6, ln 10). By filling the aneurysm with the occluding agent, the cavity of the aneurysm is occluded, and endothelialization across the ostium (neck) will occur via natural cell ingrowth. The balloons are introduced intravascularly (which Applicants call endovascularly) via catheters; because the catheters are intended for intravascular delivery, they are necessarily of a size which may be considered 'microcatheters' (See Helm et al, col. 8, ln 42-55). Though not explicitly stated, the method of Helm et al necessarily involves a first step of identifying an aneurysm for treatment.

In a preferred embodiment Helm et al disclose a biocompatible film may be provided on the first and/or second balloons (See Helm et al, col. 6, ln 11-col. 7, ln 67). The biocompatible films can comprise one or more biocompatible materials including polymers, such as collagen, laminin, elastin, as well as growth factors (See particularly col. 6, ln 17-27). The biocompatible films may further have cells seeded thereupon, including endothelial cells. The cells may be derived from the patient to be treated (thus autologous endothelial cells may be used) (See particularly col. 6, ln 32-39). The cells may be grown to confluence on the balloon prior to delivery to the treatment site (See particularly col. 7, ln 1-22). Helm et al state that when a biocompatible film is provided on the second balloon, the film will adhere to the stabilized occluding agent and therefore separate from the second balloon upon removal to remain *in vivo*. The portion of the film which remains *in vivo* aids in sealing the ostium, and cells contained within the film necessarily integrate into the existing blood vessel wall; this results in improved occlusion, enhanced migration, adhesion and growth of new cells, generally 'enhancing endothelialization across the aneurysm ostium (See particularly, col. 7, ln 39-67).

In the above preferred embodiment, the second balloon, which may be coated with biocompatible films comprising a confluent layer of cells (including autologous endothelial cells) and growth factors, is considered to read on the aneurysm maintenance device coated with a biocompatible material comprising cells.

The portion of the cell-seeded biocompatible film which remains *in vivo* may, itself, be considered to read on the polymer scaffold comprising the cells, as the biocompatible film may comprise polymers such as collagen. Alternatively, the occluding agent may be considered to read on the polymer scaffold comprising the cells, as the portion of the cell-seeded biocompatible film adheres to the stabilized occluding agent, and thus the occluding agent functions as a scaffold for those cells; it is noted the occluding agent may comprise any of a number of biocompatible polymeric materials, including fibrin (See Helm et al, col. 9, ln 5-col. 10, ln 13, particularly col. 9, ln 45 "fibrin glue").

Therefore the method of Helm et al anticipates the claimed subject matter.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALLISON M. FORD whose telephone number is (571)272-2936. The examiner can normally be reached on 8:00-6 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Allison M. Ford/
Examiner, Art Unit 1651